Medicare Clinical Laboratory Fee Reporting Requirement

Background

Starting Jan. 1, 2018, rates on the Medicare Clinical Laboratory Fee Schedule (CLFS) will be based on the national volume-weighted median payment rate paid by private payers. Private payers typically pay less than the CLFS rates for the same test, and Medicare expects to save $5.2 billion over the next decade as a result of this change.

CMS will determine the new payment rates by analyzing payment information that certain clinical laboratories (called “applicable laboratories”) will be required to report to the federal government on a tight timetable, in the first quarter of 2017. “Applicable laboratories” may be independent laboratories, hospital-based laboratories, and physician office laboratories. Because more than 90% of the potentially applicable laboratories are located in physicians’ offices, determining whether a physician office laboratory has to report or not — and documenting the rationale — is a critical action to take before Jan. 1, 2017.

Applicability of the Reporting Requirement

If your office’s lab is an “applicable lab”, then you must submit reports in January. Determining applicability is tricky and guidance is scarce. CMS issued a Final Rule (81 Federal Register 41036) on June 23, 2016, that defines an applicable laboratory:

1. Using its National Provider Identifier (NPI), the lab with a CLIA certificate of compliance or waiver is considered an applicable laboratory if more than 50 percent of its total Medicare revenues are received from payments under the CLFS and physician fee schedule (PFS). Of the total Medicare revenue received by the CLIA-certified or CLIA waived laboratory’s billing NPI from all sources, more than half (50%) must have come from the CLFS or the Physician Fee Schedule (PFS). Here, “all sources” includes Medicare revenue from hospital DRGs, outpatient Ambulatory Payment Classifications (APCs) and Medicare Advantage plans, as well as the CLFS and PFS. Note that this “majority of Medicare revenues” test counts revenue from both the PFS and the CLFS, while the low expenditure threshold (#2 below) only counts CLFS revenue.

2. An applicable laboratory would also have to receive at least $12,500 in Medicare revenues received for CLFS services revenue from claims with final payments made in the Jan. 1, 2016, to June 30, 2016 (the data collection period). The $12,500 will not apply to certain laboratories with respect to the advanced diagnostic laboratory tests (ADLTs) they offer and furnish. This “low expenditure threshold” will exclude many physicians’ offices that perform laboratory tests. Note that anatomic pathology procedures are paid on the Physician Fee Schedule (PFS), not the CLFS. CMS has posted a list of the CLFS HCPCS codes on its website.

For entities with multiple locations (and CLIA certificates), the “applicable laboratory” determination is made at the level of the National Provider Identifier (NPI), but data reporting for a group of NPIs that share a Taxpayer Identification Number (TIN) must be performed by the TIN-level “reporting entity.”

If an organization with five CLIA-certified or CLIA-waived laboratories bills under five different NPIs, they are considered to be five separate laboratories, but if they all bill under the same NPI, they are considered to be a single laboratory with the combined revenue of all five.
For most physician offices, it is likely that the PFS or CLFS make up the majority of Medicare revenue, thereby triggering the reporting requirement, while many hospitals receive most of their Medicare revenue through the DRG and APC bundled payments, which are not included in the numerator.

**If your laboratory meets the criteria above, it is an applicable laboratory**, and your practice will be required to submit payment data to CMS. If you determine that it is not, you are not required to participate in this reporting process; further, CMS’ rules prohibit voluntary reporting.

*If your lab is an “applicable laboratory,” what is required?*

Prepare to collect “applicable information” for the initial data collection period. Applicable information includes:

1) a specific HCPCS code,
2) the final payment rate(s) paid by each private payer (net of price concessions) for that code, and
3) the volume of tests that were paid at each private payer rate.

This involves a registration process for the person in your group who will report the data and for the person in the group who will certify the accuracy of the data.

**Reporter.** The reporter makes the initial registration. The registration portal is located at [https://portal.cms.gov](https://portal.cms.gov). The reporter must be enrolled in PECOS and such enrollment must be verified. All users must register to obtain a valid CMS EIDM user name and password. User names are six characters or more and different from one’s CMS Enterprise User Administration (EUA) user name, which is only 4 characters. Registration opens on November 14, 2016.

**Certifier.** A senior executive (the president, CEO, CFO or their direct report) must certify that the information is accurate, complete and truthful, and meets all of the reporting parameters. Failure to report, or mistakes or omissions in reporting, is punishable by a civil monetary penalty of up to $10,017 per day, per violation, and could be the basis for prosecution under the False Claims Act.

*What is required to be reported?*

Private payers include group and individual market health plans, Medicare Advantage plans and Medicaid managed care plans, and reports should include payments from secondary payers. If patients paid cost-sharing, these amounts also must be reported, but the names of the plans or of patients should not be reported.

Applicable laboratories are not required to report denied claims (“zero payments”), capitated payments and remittances in which the payer grouped test-level payments into a single encounter-level payment. If a test is paid using an unlisted or Not Otherwise Classified (NOC) code, it cannot be reported, either.

Once gathered, report applicable information to CMS during the “data reporting period” of Jan. 1 to March 31, 2017. This process will be repeated every three years thereafter.
More information will be forthcoming. For example, CMS is reportedly building a data collection system with a Web portal for laboratories to upload their data, but the desired format for the data is unknown at this time. CMS is expected to issue further guidance on the reporting requirements this fall.

Here are links to more information.

CMS’ home page on PAMA regulations: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html


The TMA legal department cannot advise members as to whether their labs are required to report.